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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,356	12/11/2006	Richard R. Bott	DOG 0101 PA/35319.68	9374

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EXAMINER	
ASHBY, TANIA L	
ART UNIT	PAPER NUMBER
4131	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,356	BOTT ET AL.	
	Examiner	Art Unit	
	TANIA ASHBY	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :31 July 2006, 10 September 2008, 5 February 2009 .

DETAILED ACTION

Priority

The instant application, filed April 17, 2006 is a national stage entry of PCT/US04/35686, filed October 27, 2004. This application claims benefit to the prior provisional application 60/514709, filed October 27, 2003. The earliest effective date afforded to the instant claims is October 27, 2003.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on July 31, 2006 and February 5, 2009 have been noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

The information disclosure statement filed September 10, 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 101/112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 90 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 90 provides for the use of the controlled release composition of claim 72, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 90 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 79 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Claim 79 recites the term "enzyme" of which the accepted meaning is "any of numerous complex proteins that are produced by living cells and catalyze specific biochemical reactions at body temperatures". However, the claim lists non-enzyme proteins such as antibodies, polypeptides, peptides, hormones, cytokines, growth factors, and biological modulators as "enzymes." Thus, it is unclear what applicants regard as enzymes since the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 72-79, 81, 83-84 and 87-88 rejected under 35 U.S.C. 102(b) as being anticipated by Foldvari et al. (U.S. Pat. 5,993,852, issued November 30, 1999, cited on Applicant's IDS dated September 10, 2008).

The Foldvari et al. reference discloses a composition that includes an oil-in-water (O/W) emulsion for transdermal administration (abstract). The Foldvari et al. reference also teaches a transdermal device for administration of the composition (column 2, lines 41-54).

Regarding claim 72, the Foldvari et al. reference teaches a composition comprised of an oil-in-water emulsion that additionally includes an immunogen (i.e. protein, column 4, lines 15-16) incorporated into the emulsion. The emulsion is disclosed in column 5, lines 64-67 as having a hydrophilic solvent (i.e. being substantially free of lipophilic solvent). The membrane and the reservoir taught in Figure 3A of the Foldvari et al. reference together form the controlled release layer of the composition. The composition is furthermore taught in the abstract to be administered transdermally (i.e. topically to the skin). Although Foldvari et al. does not disclose the emulsion as being formed by mechanical inversion of a water-in-oil emulsion, the process by which the composition is made is irrelevant where the composition disclosed by the prior art is structurally equivalent to the composition that Applicant is claiming. In the instant case, the formation of the emulsion by mechanical inversion does not afford any structural differences to the claimed composition (i.e. the composition is comprised of identical elements) and therefore the composition disclosed by the prior art anticipates the claim.

Regarding claims 73 and 83-84, the Foldvari et al. reference teaches the active agent (i.e., immunogen) as being able to be entrapped in the water phase (hydrophilic phase) of the oil-in-water emulsion depending on the physiochemical properties of the

immunogen (column 4, lines 57-65). The reference furthermore details the hydrophilic phase as being prepared in Example 1 by mixing components including propylene glycol (carrier) and water. The silicone component, more specifically polydimethylsiloxane, is in the form of a pressure sensitive adhesive and is taught in column 9, lines 51-53.

Regarding claim 74, column 6, line 62 of the Foldvari et al. reference teaches the inclusion of a surfactant in the emulsion.

Regarding claim 75, column 5, lines 64-67 of the Foldvari et al. reference teaches numerous carriers including propylene glycol.

Regarding claim 76, column 14, lines 22-26 of the Foldvari et al. reference teaches the propylene glycol (carrier) in solution with water.

Regarding claims 77-79, the protein taught in Foldvari et al. is a natural enzyme, more specifically egg lysozyme (a hydrolase) (column 13, lines 7-9).

Regarding claim 81, the Foldvari et al. reference discloses a skin permeation enhancer in column 8, lines 19-20 that has the ability to enhance the penetration of the entrapped antigen (i.e. active). Although the reference does not specifically state that the penetration enhancer is a dispersing agent, absent any other explicit definition provided by Applicant in the specification, dispersing agent is interpreted to mean a substance that facilitates the distribution of the active agent. A skin permeation enhancer, like the one taught by Foldvari et al., would necessarily function as such.

Regarding claim 87, the controlled release layer is formed from the reservoir 42 and the outer membrane 46 that retains the formulation within the reservoir in Figure 3A

of the Foldvari et al. reference and additionally in column 9, lines 15-23. The adhesive layer 50 is also set forth in Figure 3A and is adjacent to the controlled-release layer (comprising both the membrane and the reservoir). Figure 3A also shows an additional backing layer 42.

Regarding claim 88, Figure 3C of the Foldvari et al. reference teaches a third transdermal device wherein the reservoir 82 is composed of an absorbent sponge or a permeable polymer (also considered the controlled release layer), that is in direct contact with the skin (column 10, lines 10-13). The transdermal device furthermore comprises an adhesive layer 86 and an additional layer 88 (backing layer) where the additional layer is adjacent the adhesive layer but spaced from the controlled release layer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foldvari et al. (U.S. Pat. 5,993,852, issued November 30, 1999) and Mackles et al. (U.S. Pat. 5,178,881, issued January 12, 1993).

The Foldvari et al. reference teaches a composition that includes an oil-in-water (O/W) emulsion for transdermal administration (abstract). The Foldvari et al. reference also teaches a transdermal device for administration of the composition (column 2, lines 41-54).

The Foldvari et al. reference does not teach the controlled release layer (formed from the controlled release composition) as being free of water.

The Mackles et al. reference teaches anhydrous topical compositions that dry rapidly on contact (title).

Regarding claim 89, the Mackles et al. reference teaches anhydrous topical bases that function as delivery systems for medications (column 1, lines 24-25) further in the form of an oil-in-water emulsion (column 1, lines 43-47).

It would have been obvious to a person having ordinary skill in the art, at the time of invention, to be motivated to combine the teachings of the Foldvari et al. reference with the anhydrous feature of the topical composition taught by Mackles et al. because the Mackles et al. reference discusses several disadvantages of the presence of water

in the composition. More specifically, in column 1, lines 67-68, Mackles et al. teaches that the presence of water can result in active ingredient instability. This would be particularly disadvantageous in the instant invention because the instant invention is drawn to a controlled release composition that in some embodiments comprises an active ingredient. It is especially important in controlled release systems that the active ingredient be stable to ensure more optimal drug delivery.

Claims 80, 82 and 85-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foldvari et al. (U.S. Pat. 5,993,852, issued November 30, 1999) and Bott et al. (U.S. 2003/0180281, filed March 10, 2003) as evidenced by Kanios et al. (U.S. Pat. 6,337,086, issued January 8, 2002).

The Foldvari et al. reference teaches a composition that includes an oil-in-water (O/W) emulsion for transdermal administration (abstract). The Foldvari et al. reference also teaches a transdermal device for administration of the composition (column 2, lines 41-54).

The Foldvari et al. reference does not teach any of the specific enzymes recited in claim 80, nor a dispersing agent comprised of a silicone-based surfactant, nor a pressure sensitive adhesive comprising the reactant product of claim 85 or the silicate resin further defined in claim 86.

The Bott et al. reference teaches a topical preparation containing a silicone matrix, a hydrophilic carrier such as propylene glycol, polyethylene glycol, poloxamer, glycerin, alcohol, polyhydric alcohol, and water, and combinations thereof, and at least

one active agent for release from the preparation ([0060], [0008] and claim 11), which forms oil-in-water or water-in-oil emulsion [0008].

Regarding claim 80, the Bott et al. reference teaches proteases such as protease A or protease B in embodiment [0049] of the invention.

Regarding claims 82 and 85-86, the Bott et al. reference teaches a silicone matrix that is selected from high molecular weight polydimethylsiloxanes, loosely or lightly cross-linked silicone elastomers, fillerless elastomers, cellular elastomers, silicone rubbers, silicone pressure sensitive adhesives, and combinations thereof. It discloses the silicone matrix may be comprised of a silicone pressure sensitive adhesive (silicone PSA), such as a silicate resin in silicone polymers, which includes the reaction product of a hydroxyl endblocked polydimethylsiloxane polymer and a hydroxyl functional silicate resin ([0041], evidenced by US patent 6,337,086, the disclosure of which is incorporated by reference for their teaching of silicone PSAs for use in US Patent Publication 2003/0180281).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the silicone component and the proteases (more specifically protease A or protease B) taught by Bott et al. for the emulsion taught by Foldvari et al. with a reasonable expectation of success because the Bott et al. reference teaches that silicone components aid controlled and sustained release of active agents (embodiment [0002]) and furthermore teaches that wound dressings comprising a biochemical agent and a silicone matrix accelerate the healing of the skin (embodiment [0004]). With regard to the specific enzymes (i.e. proteases),

embodiments [0007 and 0051] of the Bott et al. reference also suggest that the silicone matrix will be successful in the release of such proteases and that the proteases aid in general wound healing as well as clotting formation or removal. This feature is particularly advantageous to the instant invention because the instant invention is drawn to a controlled release composition for topical application and in some embodiments, a multi-layer dressing that could function as a wound dressing.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TANIA ASHBY whose telephone number is (571)270-1348. The examiner can normally be reached on Monday through Friday, 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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